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| APPLICATION NO. FILING DATE | | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. 4051 | | |
|-----------------------------|--|-------------------------|---------------------|-----------------------|--|--|
| 10/076,785 02/15/2002 | | Saverio Carl Falco | BB1336 USCNT | | | |
| 23906 | 7590 11/28/2003 | | EXAMINER | | | |
| | NT DE NEMOURS AND | KERR, KATHLEEN M | | | | |
| | ΓENT RECORDS CENTER ILL PLAZA 25/1128 | ART UNIT | PAPER NUMBER | | | |
| 4417 LANC. | ASTER PIKE | 1652 | | | | |
| WILMINGT | ON, DE 19805 | DATE MAILED: 11/28/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | Applicatio | n No | Applicant(s) | | | |
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| | | 10/076,785 | | | FALCO ET AL. | | | | |
| | Offic | Action Summary | } | Examiner | | Art Unit | | | |
| | | • | | Kathleen M | 1 Kerr | 1652 | | | |
| | - The MAIL | ING DATE of this commu | ınication app | | | | ddress | | |
| Period fo | | | | | | | | | |
| THE N - Extendenter S - If the I - If NO - Failure - Any re | MAILING D sions of time m SIX (6) MONTH period for reply period for reply e to reply within eply received b | STATUTORY PERIOD ATE OF THIS COMMUL hay be available under the provision of from the mailing date of this conspecified above is less than thirty is specified above, the maximum in the set or extended period for rely the Office later than three month digustment. See 37 CFR 1.704(b) | NICATION. Ins of 37 CFR 1.13 Instruction (30) days, a reply statutory period w ply will, by statute. | 66(a). In no ever within the statu ill apply and will cause the appli | nt, however, may a reply b tory minimum of thirty (30) I expire SIX (6) MONTHS f cation to become ABANDO | be timely filed) days will be considered time from the mailing date of this of ONED (35 U.S.C. § 133). | | | |
| 1)🖂 | Responsiv | re to communication(s) f | iled on <u>31 Ju</u> | ly 2003. | | | | | |
| 2a) | This action | This action is FINAL . 2b)⊠ This action is non-final. | | | | | | | |
| |) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Disposition | on of Clair | ms | | | | | | | |
| 4) 🖂 | 4)⊠ Claim(s) <u>1-30</u> is/are pending in the application. | | | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | |
| 5) | 5) Claim(s) is/are allowed. | | | | | | | | |
| 6)[| 6) Claim(s) is/are rejected. | | | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | | | |
| 8)🖂 | Claim(s) <u>1</u> | -30 are subject to restric | ction and/or e | election requ | uirement. | | | | |
| Application | on Papers | 3 | | | | | | | |
| 9) 🗌 🗆 | The specifi | cation is objected to by | the Examiner | г. | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | | |
| Priority u | nder 35 U | .S.C. §§ 119 and 120 | | | | | | | |
| * S 13) [A sii 37 a) 14) [A | All b) 1. Cert 2. Cert 3. Cop app ee the atta cknowledg nce a spec 7 CFR 1.78 cknowledg | dgment is made of a claid Some * c) None of tified copies of the prioritities of the certified copies of the International Notes of the certified copies of the International Notes of the Certified Copies of the Certified Copies of the Certified Copies of the International Notes of the Inter | ty documents by documents s of the prioritional Bureau tion for a list of for domestic ded in the firs anguage pro- | s have been to have been ity docume (PCT Rule of the certific priority un t sentence visional app | n received. In received in Application have been received 17.2(a)). It is ideal copies not received 35 U.S.C. § 11 of the specification polication has been der 35 U.S.C. §§ 1 | cation No eived in this National eived. 19(e) (to a provisional n or in an Application received. 120 and/or 121 since | al application) n Data Sheet. e a specific | | |
| Attachment | | | | | | | | | |
| 2) Notice | of Draftsper | es Cited (PTO-892) son's Patent Drawing Review sure Statement(s) (PTO-1449) | | | | nary (PTO-413) Paper No nal Patent Application (PT | | | |

Application/Control Number: 10/076,785

Art Unit: 1652

Page 2

DETAILED ACTION

Application Status

1. By virtue of a preliminary amendment filed February 15, 2002, Claims 1-30 are pending in the instant application.

Restriction

- 2. Restriction to one of the following inventions (noting SuperGroups *and* Groups below) is required under 35 U.S.C. § 121:
- SuperGroup A. Claims 1-13, 24-30, drawn to polynucleotides, chimeric genes, host cells, viruses, and methods of transforming a cell, classified in class 435, subclass 468.
- SuperGroup B. Claims 14-18, drawn to polypeptides, classified in class 435, subclass 193.
- SuperGroup C. Claims 19-21, drawn to methods of selecting a polynucleotide that affects proteinase expression, classified in class 435, subclass 23.
- SuperGroup D. Claims 22-23, drawn to methods of obtaining a nucleic acids encoding proteinases, classified in class 435, subclass 6.

For each of the above SuperGroups, the following Groups also apply:

Group I, related to corn calpain p94 subunit, SEQ ID NOs: 1, 2, 7, 8.

Group II, related to rice calpain p94 subunit, SEQ ID NOs: 3, 4, 9, 10.

Group III, related to soybean calpain p94 subunit, SEQ ID NOs: 5, 6, 11, 12.

Group IV, related to rice cysteine protease 1, SEQ ID NOs: 13, 14, 17, 18.

Group V, related to wheat cysteine protease 1, SEQ ID NOs: 15, 16, 19, 20.

Group VI, related to soybean cysteine protease 2, SEQ ID NOs: 21, 22, 23, 24.

Group VII, related to corn CLP ATP binding subunit, SEQ ID NOs: 25, 26, 31, 32.

Group VIII, related to rice CLP ATP binding subunit, SEQ ID NOs: 33, 34, 27, 28.

Group IX, related to wheat CLP ATP binding subunit, SEQ ID NOs: 29, 30, 35, 36.

Group X, related to corn CLP proteolytic subunit, SEQ ID NOs: 37, 38, 47, 48.

Group XI, related to rice CLP proteolytic subunit, SEQ ID NOs: 39, 40, 49, 50.

Group XII, related to soybean CLP proteolytic subunit, SEQ ID NOs: 41, 42, 51, 52.

Group XIII, related to wheat CLP proteolytic subunit, SEQ ID NOs: 43, 44, 45, 46, 53, 54, 55, 56.

Thus, each invention is a SuperGroup further restricted to one of the Groups above. The total number of invention is four SuperGroups multiplied by thirteen Groups, fifty-two Groups — one of which must be elected in response to the instant Office action.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I-XIII are all related as plant proteinase sequences. However, each of the above Groups is distinct, each from the other, based on the different structures and functions of the sequences. No common structure, such as a consensus sequence, of plant calpain 94 subunit is disclosed. Thus, no genus is defined structurally, and each disclosed structure is distinct. No specific, common function is described since the catalytic activity of a cysteine protease 1 is distinct from the catalytic activity of a CLP proteolytic subunit. Thus, Groups I-XIII contain subject matter that is distinct, each from the other. While any of these Groups are identically classified within their respective SuperGroups, restriction for examination purposes as indicated is proper because the search required for SuperGroup A, Group I, is not required for SuperGroup A, Group II, based on the distinct structural limitations in the claims as well as the distinct source species found in the disclosure.

The DNA of SuperGroup A is related to the enzymes of SuperGroup B by virtue of the fact that the DNA encodes the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because they are wholly different in structure and function. DNA is comprised of nucleotide bases while enzymes are comprised of amino acids. DNA function to encode proteins while enzymes function to catalyze reactions. Moreover, the enzyme product

Application/Control Number: 10/076,785

Art Unit: 1652

can be made by other and materially distinct processes, such as purification from a natural source; and the DNA product can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, members of SuperGroups A and B are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

SuperGroups A and C are related as product and process of use since a portion of the polynucleotides in SuperGroup A are used in the methods of SuperGroup C. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polynucleotides of SuperGroup A can be used for a materially different process of using the product, such in the recombinant production of the encoded proteinase, which methods are distinct from those of SuperGroup C due to distinct method steps, reagents, and products. Therefore, members of SuperGroups A and C are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

SuperGroups A and D are related as product and process of use since a portion of the polynucleotides in SuperGroup A are used in the methods of SuperGroup D. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

Art Unit: 1652

product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polynucleotides of SuperGroup A can be used for a materially different process of using the product, such in the recombinant production of the encoded proteinase, which methods are distinct from those of SuperGroup D due to distinct method steps, reagents, and products. Therefore, members of SuperGroups A and D are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

SuperGroup B is related to SuperGroups C and D by virtue of the DNA being used in the methods of C and D encodes the proteins of SuperGroup B. However, the proteins and neither made nor used in the methods. Therefore, members of SuperGroup A are patentably distinct from members of SuperGroups C and D. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

SuperGroups C and D are related as methods of using portions of DNA encoding plant proteinases as defined by SuperGroup A. However, C and D require distinct methods steps to produce a distinct product. Therefore, members of SuperGroup C are patentably distinct from members of SuperGroup D. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Application/Control Number: 10/076,785 Page 6

Art Unit: 1652

Notice of Possible Rejoinder

4. Because the method claims of SuperGroups C and D do not use the entire portion of the polynucleotides claimed in SuperGroup A, said methods are not subject to rejoinder because they are not methods of using the products. The Examiner notes that rejoinder exists because of *In re* Ochiai, and *In re* Brouwer (see also M.P.E.P. § 821.04), which note that no further search is required for claims to an allowable product. In the case of Claims 19-21, the product used in the claims, namely a portion of Claim 1, for example, may not be an allowable product. The Examiner notes that if Claims 19-21 were amended to be drawn to using the polynucleotide products, as they would be allowed, such claims would be subject to rejoinder.

Election

5. A telephone call was made to Lynne Christenbury on November 25, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Art Unit: 1652

Conclusion

Page 7

6. There are fifty-two inventions in the instant restriction – one of which must be elected in response to the instant Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

November 25, 2003

Kathl L